REMARKS

Claims 1-42, 44, 45 and 48-52 are currently active.

Claim 52 has been added. Antecedent support for Claim 52 is found in Claims 1-3 and 8.

Claims 2, 3, 30 and 31 have been canceled.

Claims 43, 46 and 47 have been canceled due to the finality of the restriction requirement.

The drawings have been amended to show the inflow valve and a perfusion valve with respect to Claim 21.

The Examiner has rejected Claim 22 under 35 U.S.C. 112, second paragraph. Claim 22 now depends on Claim 20. Accordingly, there is antecedent basis for "the controller".

The Examiner has rejected Claims 1-6, 29-34, 48 and 51 as being anticipated by Hirose. Applicants respectfully traverse this rejection.

Referring to Hirose, there is disclosed an apparatus for assisting blood circulation. Hirose teaches an inflow tube 1. An inlet for blood 2 is made in the tip of the inflow tube 1 for taking in blood. A balloon 4 is attached at the tip of the inflow tube 1. The balloon 4 is connected to a balloon connector 6 and can be inflated or deflated by charging or discharging helium through the balloon connector 6. When the balloon 4 is inflated after the inflow tube 1 is inserted through the septum, the inflow tube is prevented from detaching. The connector 5 to the pump is attached to the base end of the inflow tube 1 end.

At the tip of an outflow tube, an opening for sending out blood is made. The balloon 10 is attached at a short distance from the tip. The balloon 10 is connected to a balloon connector 12 and can be inflated or deflated by charging or discharging helium gas through the balloon connector 12. The balloon 10 is the balloon utilized for counter pulsation and can deliver blood to the whole parts of the body with pulses. A flap valve 11 is attached to the side of the tube at an upstream location and before the balloon 10. See column 8, lines 56-69.

A tip of a penetration core 13 has a shape with a curvature so that it can easily penetrate the fossa ovalis. The guide wire 14 is inserted to the inside of the penetration core 13, and at the tip of the guide wire, the penetration needle 15 is attached to facilitate the penetration through the fossa ovalis. The guide wire 14 moves along the inside of the penetration core 13 and can place a penetration needle 15 to the tip of the penetration core 13. The penetration core 13 can move along the inside of the inflow tube 1 and is inserted to the tip of the inflow tube 1. The inflow tube 1 takes the shape with the curvature in accordance with the shape of the penetration core 13. See column 9, lines 1-19.

The inflow tube 1 is inserted in the body from the femoral vein 25 to the left atrium 21 through the under large vein 16, the right atrium 18 and the fossa ovalis 19. The outflow tube 8 is inserted from the femoral artery 26 to the aorta 24. The blood taken in by the inflow tube 1 is delivered to the aorta by the outflow tube 8 through the vibration blood pump. The blood is delivered in a synchronized action with the pulse of the heart so that the delivery of blood makes no load on the heart. The inflation and deflation of the balloon 10 is synchronized with the pulse of the heart by utilizing a driving apparatus which can synchronize the movement of the pulse of the heart. The outlet of blood 11 made at the upstream location of the outflow 28 is placed at the branching point of the aorta and the formal artery. A valve 29 is positioned in the outlet tube 8, downstream of the flap 11 at the upstream location. The control circuit controls the operation of the pump. See column 9, lines 2-60.

The inflow tube 1 is inserted in the body from the femoral vein 25 into the right atrium 18 through the larger vein 16. The outflow tube 8 is inserted from the femoral artery 26 to the aorta 24. The blood taken in by the inflow tube 1 is delivered to the aorta through the vibration blood pump and the oxygen exchanger. The oxygen exchange is placed after the vibration blood pump. The vibration pump performs the pumping function by the vibration of a tube to the axial direction of the tube. The vibrating tube 32 is supported by a supporting spring 33 from both sides and a vibrating valve is attached at an end of the tube. The tube is vibrated to the axle direction of the tube by a magnetic force. The vibrating forces generated by varying the bias magnetic field generated by a permanent magnet 34 at the circumference of the vibrating tube 32 by the action of the magnetic field of electromagnetic coil 35. Blood is sucked in at the inlet 37 by increasing blood pressure by the action of the vibration of the vibrating tube 32, the spring valve is opened and the blood in the vibration tube is transferred to the space of the spring valve. When the pressure in the vibration tube is reduced, the valve is closed and the blood in the space of the spring valve is discharged from the outlet 38 by the piston effect of the leftward movement of the vibrating tube 32.

There is no teaching or suggestion anywhere that the blood pump taught by Hirose is within 3 ft. of where the transseptal cannula and the output cannula are positioned to enter the patient. Hirose is completely silent about where the blood pump is disposed relative to the patient. Accordingly, the Examiner is reading a limitation into the teachings of Hirose

which are not present. For this reason, amended Claim 1 is patentable over Hirose. Claims 4-6 are dependent to parent Claim 1 and are patentable for the reasons Claim 1 is patentable.

The Examiner on page 4, lines 5 and 6 states that Hirose teaches a transseptal clamp mechanism 5 for clamping the blood pump to the transseptal cannula 1. A review of Hirose shows that Hirose only teaches that element 5 is a connector. A connector has nothing at all to do with a clamp. For instance, as stated on page 15 of the specification of applicants, the clamp is used to prevent blood loss. This is different than a connector. There is nothing indicated under the basic definition of a connector that it acts as a clamp. A connector simply connects two pieces together, which is quite different from the function and definition of a clamp. Amended Claim 29 has the specific limitation of clamping a transseptal clamp mechanism to the transseptal cannula and the blood pump to avoid undesired disconnection of the blood pump and transseptal cannula and undesired leak of the connection joint. Accordingly, Claim 29 is patentable over Hirose.

Claims 31-34 are dependent to parent Claim 29 and are patentable for the reasons Claim 29 is patentable. Moreover, Claim 31 is patentable for the reasons Claim 1 is patentable in regard to the blood pump being within 3 ft. of where the transseptal cannula and the perfusion cannula are inserted into the patient. Additionally, Claim 33 has the limitation

of adjusting the flow of blood pump with a controller connected to the blood pump. Hirose does not teach or suggest this limitation.

Referring to Fonger, there is disclosed a percutaneous transseptal left atrial cannulation system. Fonger teaches a radio-opaque catheter 5 contains a guide wire 17 and a needle assembly 9, 11, 15 which can ultimately be advanced through the orifice 13 in the catheter distal end. The needle assembly includes a needle wire 9, a first metal tube 11 which can advance through the catheter orifice 13 and an outer metal tube 15 which cannot extend through the catheter orifice 13, and a single metal tube with a narrowed distal end such that a predetermined length of tube projects out of the catheter orifice but a thicker tube which is stopped at the orifice may be substituted for tubes 11 and 15. The smaller inner metal tube fits inside the outer metal tube. The smaller tube is the outer tube and protrudes out the end for a fixed distance and has a rounded end to prevent scraping within the catheter 5. See column 4, line 52-column 5, line 23.

Fonger teaches the needle assembly punctures the septum and subsequently acts as a stiff curved guide to direct both the catheter and cannula across the septum and into the left atrium. The needle assembly has a stiffness sufficient to guide the catheter and cannula over it as well as to have adequate flexibility to the passage through the veins in route to the right atrium. See column 5, lines 29-36. A peal-away sheath assembly is comprised of hub 1

which is molded into tube 31 with a tapered end. Both the hub and the tube were scored in such a way that they will tear longitudinally in half and can be easily removed from the cannula. The peal-away sheath covers the hole 7 in the cannula 3 during the initial stage of percutaneous insertion when the cannula traverses the subcutaneous fat. It shields the cannula holes from accumulating particulate fat debris prior to reaching the bloodstream. Once a cannula is with the femoral vein, the sheath is pulled back and peeled away. See column 5, lines 50-60. The cannula coupling assembly 99 is comprised of cannula hub 19, barbed tube connector 21, producer plug 23, male connector 25, bushing holder 49, bushing 47 and closing ring 27. The cannula hub 19 is comprised of two components 18 and 20. The distal component 20 of hub 19 is flexible and can be clamped. The cannula hub 19 distal end is fixed to the cannula 3. The cannula hub 19 proximal end is rigid and fixed to a rigid, barbed tube connector 21. The producer plug 23 is attached to the tube connector 21. The tube connector 21 is comprised of a proximal component which is attached to the inner portion of a distal opponent.

The needle assembly proximal end includes a hub 29 attached to the metal tubes, a pointer 33 for indicating the angular orientation of the curved distal end of the needle assembly, and a molded hub 35 attached to the needle wire 9. When display information is combined with a pointer indication, the new orientation can be determined. The integral configuration of the system allows the protected delivery of the needle assembly to the right

atrium of the heart over the guide wire. The guide wire 17 is pulled back and the needle wire 9 and the inner metal tube 11 are advanced to affect the transseptal puncture of the heart. The guide wire 17 is comprised of a stainless steel spring wire wrapped around a separate core wire. The guide wire guides the catheter to the right atrium and once the catheter is in the left atrium it can be used to access the distance to the collateral left atrial wall. See column 6, lines 26-50.

Fonger teaches the cannulation system is inserted into the femoral vein using a conventional breakaway needle through which guide wire 17 is threaded. The transseptal cannulation system is advanced over guide wire 17 into the femoral vein. Both the guide wire and needle are long enough to allow a substantial length to extend out of the body at the groin for manipulation even when the distal ends of the guide wire and needle are positioned in the heart. Once the cannula holes 7 pass into the bloodstream, the sheath 1, 31 is pulled back and peeled away. The guide wire 17 assists in guiding the cannulation system to the right atrium of the heart under fluoroscopic guidance. Once the catheter is in the right atrium with the cannula at the level of the diaphragm, the guide wire is withdrawn and the catheter and the needle assembly is advanced to the septum. The needle is dragged down to the enter arterial system and to the fossa ovalis area of the septum. The ridge surrounds the region and provides a tactile and visual indication of falling into the fossa. The fluoroscopic display of the needle tip and the hub pointer on the needle assembly provide confirmation of proper

orientation. When the needle is properly positioned, the needle wire 9 is advanced and the septum is pierced. See column 6, line 67-column 7, line 27.

The appearance of red oxygenated blood from the left atrium in the cannula indicates the tip of the cannula is in the left atrium. The fluoroscopic display provides an indication of the actual cannula location. When the cannula is properly positioned, the guide wire, needle assembly and catheter are withdrawn and removed. Oxygenated blood from the left atrium drains through the venous cannula 3 to pump 37. A centrifugal pump which can pump blood safely for several days is taught by Fonger. However, any conventional pump can be used. The blood is returned to the body by means of an atrial cannula 41 inserted into the femoral artery. See column 7, lines 28-50.

There is no teaching or suggestion anywhere that the blood pump taught by Fonger is within 3 ft. of where the transseptal cannula and the output cannula are positioned to enter the patient. In this claimed embodiment, applicants are very careful to choose to place the blood pump within 3 ft. of where the transseptal cannula and the output cannula are positioned to enter the patient to eliminate the need for heating of the blood. There is no recognition, need, or suggestion that the blood pump taught by Fonger is within 3 ft. of where the transseptal cannula and the output cannula are positioned to enter the patient. To reiterate, there is no teaching or suggestion, and in fact, Fonger is completely silent about where the

blood pump is disposed relative to the patient. Accordingly, the Examiner is reading a limitation into the teachings of Fonger which are not present. For this reason, amended Claim 1 is patentable over Fonger. Claims 4-6 are dependent to parent Claim 1 and are patentable for the reasons Claim 1 is patentable.

The Examiner on page 5, lines 1 and 2, states that Fonger teaches a transseptal clamp mechanism 18 for clamping the blood pump to the transseptal cannula 3. A review of Fonger shows that Fonger only teaches the cannula hub 19 is clear, hollow, and comprised of two components 18 and 20. The distal component 20 of hub 19 is flexible and can be clamped. Amended Claim 29 has the specific limitation of clamping a transseptal clamp mechanism to the transseptal cannula and the blood pump to avoid undesired disconnection of the blood pump and transseptal cannula and undesired leaks at the connection joint. Fonger is completely silent about what is meant by the fact that the distal component 20 can be clamped. That is as much as Fonger states. Claim 29, as amended, is very specific in terms of the methodology of applicants' invention of Claim 29. Moreover, Claim 29 is patentable for the reasons Claim 1 is patentable in regard to the blood pump being within 3 ft. of where the transseptal cannula and the perfusion cannula are inserted into the patient. Accordingly, Claim 29 is patentable over Fonger.

Claims 32-34 are dependent to parent Claim 29 and are patentable for the reasons Claim 29 is patentable. Additionally, Claim 33 has the limitation of adjusting the flow of blood pump with a controller connected to the blood pump. Fonger does not teach or suggest this limitation.

The Examiner has rejected Claim 7 as being unpatentable over Hirose. Claim 7 is dependent to parent Claim 1 and is patentable for the reasons Claim 1 is patentable.

The Examiner has rejected Claim 7 as being unpatentable over Fonger. Claim 7 is dependent to parent Claim 1 and is patentable for the reasons Claim 1 is patentable.

The Examiner has rejected Claims 8, 9, 18-20 as being unpatentable over Hirose in view of the Wampler. Applicants respectfully traverse this rejection.

Referring to Wampler, there is disclosed a sealless rotary blood pump. The blood pump taught by Wampler is for a totally different context and purpose than the blood pump identified by Hirose. The blood pump taught by Wampler is for permanent implantation in humans. See column 1, lines 10 and 11. This is totally contrary to the system taught by Hirose which calls for a blood pump, but which is disposed outside of the body and

specifically is only to be used for a short period of time, possibly a few weeks, as compared to the permanent implantation of the blood pump taught by Wampler.

The two systems taught by Hirose and Wampler are totally different from each other. There must be some teaching in the references themselves to combine their respective teachings, and there is none. Applicants submit the only reason that the Examiner is combining these references is from the hindsight of applicants' claimed invention. However, this is not patent law. The Examiner cannot use the applicants' claims as a road map to find the elements and the limitations of the claims in different references of the prior art, and having found them conclude that applicants' claimed invention is arrived at. There is no reason why, and there is any indication for any need for a controller in the system taught by Hirose. This follows since Hirose does not speak or comment in any way on the need for such a controller. In Hirose, the blood pump is disposed outside of the body, and the patient only has the system taught by Hirose for a short period of time relative to the time period suggested by Wampler. The patient will be resting in a bed, and not expected to be moving around and subject to different physical demands, as would be the case in a permanent implantation where a person would have to be able to move around and be subject to different pumping demands. Hirose does not concern itself with any of this. Accordingly, there is no need and thus no teaching for a controller in Hirose. There is no teaching in Wampler to apply a permanently implantable pump into the cannula outside the body pump system found in Hirose.

Furthermore, when teachings of references are combined, they must be combined in the context in which they are found. As explained above, these contexts are completely unrelated, and there is no way that the context of an implantable blood pump can be applied to a non-implantable blood pump system; which would be the case from the teachings of Wampler in regard to Hirose. Accordingly, Claims 8, 9 and 18-20 are patentable over Hirose in view of Wampler.

The Examiner has rejected Claims 8, 9, 18-20 as being unpatentable over Fonger in view of Aboul-Hosn. Applicants respectfully traverse this rejection.

Claims 8, 9 and 18-20 are patentable over Fonger in view of Aboul-Hosn for similar reasons that the same claims are patentable over Hirose in view of Wampler. Aboul-Hosn teaches a reverse flow pump system that transports fluid between different regions within the body in order to support a wide variety of surgical procedures, such as for the stabilization of surgical sites during procedures such as heart surgery. The other procedures are directed to unloading the heart, and partially or totally stopping the heart to allow procedures to be performed externally on or internally within the heart wall the chest remains unopened. See column 4, lines 6-28. Aboul-Hosn teaches that a single incision into a major blood vessel such as in the aorta can be used for the reverse flow pump to access the fluid. See column 4, lines 55-62. In all the embodiments that are taught by Aboul-Hosn in regard to the pump, a portal

is cut into the desired vessel, such as the aorta in regard to the heart for the pump to access blood.

The context of the system taught by Aboul-Hosn is distinct from the context of the system taught by Fonger. Fonger teaches to access the heart through the femoral artery without any injury to the structure of the heart. Aboul-Hosn teaches that a portal (an incision be made directly into the aorta) to access the blood in the heart to unload the heart wall while some procedure is performed directly on the heart. There is no teaching or suggestion in Fonger for any need of a controller in regard to the pump that is used. In regard to Aboul-Hosn, the use of the reverse pump is in regard to a specific type of procedure in which a decision is made directly into the heart provides no teaching or suggestion to be used with the system taught by the Fonger. As mentioned above, there must be some teaching or suggestion in the references themselves to combine the teachings of the references, and here, there is none. As above also in regard to Hirose and Wampler, the only reason to combine Fonger and Aboul-Hosn is from hindsight using applicants' claims as a road map to find the various elements of the claims in different references, and having done so, concluding that applicants' claimed invention is arrived at. However, this is not patent law. Moreover, when teachings of references are combined, they must be combined in the context in which they are found. The context of Fonger is completely distinct from the context of Aboul-Hosn. Aboul-Hosn's context requires an incision into the heart to create a portal for access of the pump to the blood

during the surgical procedure to the heart. The context of Fonger is to access the heart through the femoral artery so the heart itself is not damaged to assist the heart only for the purpose of assisting the heart. This context cannot be ignored. To apply the context of Aboul-Hosn to the context of Fonger, not only does not make sense, but changes the entire purpose of Fonger. Accordingly, Claim 1 is patentable over Fonger in view of Aboul-Hosn. Claims 8, 9 and 18-20 are dependent to parent Claim 1 and are patentable for the reasons Claim 1 is patentable.

The Examiner has rejected Claim 24 as being unpatentable over Fonger. Applicants respectfully traverse this rejection. Claim 24 is dependent to parent Claim 1 and is patentable for the reasons Claim 1 is patentable.

In addition, there is no teaching or suggestion anywhere in Fonger of a holding mechanism which holds an attaches the blood pump to the patient. This follows since there is the limitation that the blood pump is an extracorporeal blood pump disposed within 3 ft. of where the transseptal cannula and the output cannula are positioned to enter the patient. It is not obvious at all to have the holding means attached to the patient let alone be within 3 ft. of where the transseptal cannula and the output cannula enter the patient. In fact, it is quite contrary to what would be normally expected of some type of holding means that is physically attached to a structure that is remote from the patient and far enough away from the patient so

that the typically large sized pump will not be in the way of the patient or the medical staff who are assisting the patient. Accordingly, for this additional reason, Claim 24 is patentable over Fonger.

The newly added claim is patentable for similar reasons as explained above in regard to the reasons why the applied art of record does not teach a controller applied to a blood pump which is disposed within 3 ft. of where the transseptal cannula and the perfusion cannula are positioned to enter the patient, and a transseptal clamp mechanism to clamp the transseptal cannula to the pump.

In view of the foregoing amendments and remarks, it is respectfully requested that the outstanding rejections and objections to this application be reconsidered and withdrawn, and Claims 1-42, 44, 45 and 48-52, now in this application be allowed.

CERTIFICATE OF MAILING

I hereby certify that the correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231,

on 7/14/03

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Version with markings to show changes made to the claims

1. A system for assisting flow of blood by a patient's heart comprising:

a transseptal cannula adapted to be inserted percutaneously in the femoral vein and extend through the atrial septum from the right atrium to the left atrium;

outside the body

[a] an extracorporeal blood pump mechanism having a blood pump for pumping blood received from the left atrium through the transseptal cannula that has been oxygenated, the blood pump inlet connected to the transseptal cannula, the blood pump mechanism includes a transseptal clamp mechanism which clamps the blood pump to the transseptal cannula to avoid undesired disconnection of the blood pump and the transseptal cannula and undesired leaks in a connection joint formed between the blood pump and the transseptal cannula; and

a perfusion cannula adapted to be inserted percutaneously in the femoral artery for returning oxygenated blood to the arterial system of the patient, the perfusion cannula connected to the blood pump outlet, the blood pump disposed within three feet of where the transseptal cannula and the perfusion cannula are positioned to enter the patient.

4. A system as described in Claim [3] 1 wherein the blood pump mechanism includes tubing which connects the blood pump to the transseptal cannula and the perfusion

cannula and the clamp mechanism clamps the tubing between the blood pump and the transseptal cannula.

22. A system as described in Claim [21] 20 wherein the pump is a pulsatile pump having a stroke time, and the controller adjusts the operation of the blood pump by adjusting stroke time.

29. A method for assisting blood flow by a patient's heart comprising the steps of:

inserting percutaneously in the femoral vein of the patient and extending through the atrial septum from the right atrium to the left atrium a transseptal cannula;

inserting percutaneously in the femoral artery a perfusion cannula for returning oxygenated blood to the arterial system of the patient; [and]

positioning a blood pump within three feet of where the transseptal cannula and the perfusion cannula are inserted into the patient;

clamping a transseptal clamp mechanism to the transseptal cannula and the blood pump to avoid undesired disconnection of the blood pump and the transseptal cannula and undesired leaks at a connection joint formed between the blood pump and the transseptal cannula; and

pumping blood with [a] the blood pump connected to the transseptal cannula and the perfusion cannula at specified flow rates over a range of physiological pressures.

32. A method as described in Claim [31] 29 wherein the pumping step includes the step of pumping a continuous flow of blood with the blood pump.